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VIA e-FILE AND EMAIL

Hon. Shira A. Scheindlin
United States District Judge
Southern District of New York
United States Courthouse
500 Pearl Street, Room 1620
New York, NY 10007

Re: *Sekisui America Co., Ltd v. Hart*, No. 12-CIV-3479

Dear Judge Scheindlin:

We represent Defendants Richard Hart and Marie Louise Trudel-Hart (the "Harts") in the above-referenced action. The Harts respectfully request leave to submit this Surreply Letter to address two arguments raised for the first time in Plaintiffs' Reply in support of their Motion *in Limine* to Exclude Portions of the Report and Testimony of Thomas D. Becze ("Reply") (Dkt. 82): 1) that the United States Food and Drug Administration ("FDA") concluded that the 2009 Femtelle 510(k) was "destined to fail" (Dkt. 82 at 5); and 2) that Mr. Becze "did not base his rebuttal testimony on any of the material" on which Mr. Ulatowski based his opinion (Dkt. 82 at 4). The Harts also respectfully request leave to address this Court's statement, cited by Plaintiffs, that Mr. "Becze conceded at deposition that he cannot opine on the FemTel 510(k)[.]" *See* Transcript of Sept. 27, 2013 Pre-motion Conference at 24:16-22. It appears Plaintiffs may have misled the Court in this regard. Mr. Becze made no such concession.

In their Reply, Plaintiffs argue, for the first time and without citation, that the FDA concluded that the 2009 Femtelle 510(k) was "destined to fail." Dkt. 82 at 5). This is false. The FDA never reached any such conclusion. On the contrary, as the documents show, the FDA continued to encourage American Diagno stica, Inc. ("ADI") to submit information about the 510(k) until the day before Plaintiffs withdrew it. *See, e.g.*, June 28, 2010 email from the FDA to ADI, SEK01026197-203 (requesting information); June 29, 2010 letter from ADI to the FDA withdrawing 510(k) submission, SEK01169370 (withdrawing 510(k)).

Plaintiffs also argue for the first time in their Reply that Mr. Becze "did not base his rebuttal testimony on any of the material" on which Mr. Ulatowski based his opinion. Dkt. 82 at 4. This, too, is false. In the section of his report that discusses the FDA's 2009 and 2010 requests for more information, Mr. Ulatowski cites eight emails between ADI and the FDA. *See* July 3, 2013 Expert Report of Timothy A. Ulatowski at 20-24 ("V. Chronology of Interaction Between FDA and ADI.") Mr. Becze reviewed and based his opinion on these. *See* August 5, 2013 Export Report of Thomas D. Becze, Appendix A (citing SEK01026121 and SEK01026917, both of which are email chains containing the emails on which Mr. Ulatowksi opines).

Finally, Plaintiffs quote a statement made by the Court during the pre-motion conference—that Mr. Becze "conceded at deposition that he cannot opine" about the 2007 and 2009 Femtelle 510(k) submissions. *Id.* at 2-3 (citing Sept. 27, 2013 Tr. at 24:16-22). Mr. Becze never made this concession. The Court's statement appears to be based on an argument

pressed by Plaintiffs in their September 16, 2013 pre-motion letter (Dkt. 53) that "Mr. Becze could not opine on the specific circumstances of the Femtelle 510(k) submissions because he did not read" them. Dkt. 53 at 7. In support of this assertion, Plaintiffs cited two lines of Mr. Becze's deposition transcript. *See id.* (citing Becze Tr. 247:10-12). However, Plaintiffs did not include the substance of those two lines of Mr. Becze's testimony. The portion of the transcript cited by Plaintiffs states in its entirety:

10 Q. Did you ever review the Femtelle
11 510(k) submission?
12 A. No.

Mr. Becze never conceded that he could not opine about the 510(k) and nothing cited in Plaintiffs' Sept. 16, 2013 letter demonstrates otherwise. In fact, Mr. Becze repeatedly explained why he did not need to read the 510(k) submission to render his opinion. *See, e.g.*, Becze Tr. at 239:13-240:10; 240:20-241:9; 243:4-14; 244:18-24; 245:6-18; 247:24-248:5.

Respectfully submitted,

/s/

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